

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
	)	
	)	
Plaintiff,	)	
	)	Civil Action No.: 06-222 JJF
v.	)	
	)	<b>PUBLIC VERSION</b>
IMPAX LABORATORIES, INC.,	)	
	)	
Defendant.	)	
	)	

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**DECLARATION OF MARY B. MATTERER IN SUPPORT OF DEFENDANT  
IMPAX LABORATORIES, INC.'S MOTION TO COMPEL RESPONSES TO  
DEFENDANT'S REQUEST FOR ADMISSION NOS. 1-3, 31, 38, 50, 62, 67 AND 68**

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*Attorneys for IMPAX LABORATORIES, INC.*

Original Date: May 9, 2007  
Redacted Version: May 16, 2007

I, Mary B. Matterer, declare:

1. I am an attorney at the law firm of Morris James, LLP, counsel of record for Defendant Impax Laboratories, Inc. ("Impax") in the above-referenced case. I have personal knowledge of the facts set forth in this declaration.

2. I submit this Declaration in support of Defendant Impax Laboratories, Inc.'s Motion to Compel Responses to Defendant's Requests for Admission Nos. 1-3, 31, 38, 50, 62 and 67-68.

3. A true and correct copy of Impax Laboratories, Inc.'s Second Amended Responses to Wyeth's First Set of Interrogatories is attached hereto as Exhibit A.

4. A true and correct copy of Impax Laboratories, Inc.'s First Set of Requests for Admission is attached hereto as Exhibit B.

5. A true and correct copy of Impax Laboratories, Inc.'s Second Set of Requests for Admission is attached hereto as Exhibit C.

6. A true and correct copy of Wyeth's Responses to Impax Laboratories, Inc.'s First Set of Requests for Admission is attached hereto as Exhibit D.

7. A true and correct copy of Wyeth's Responses to Impax Laboratories, Inc.'s Second Set of Requests for Admission is attached hereto as Exhibit E.

8. A true and correct copy of a letter from Eric Lane, counsel to Impax, to Barbara Rudolph, counsel to Wyeth, dated May 9, 2007 is attached hereto as Exhibit F.

9. A true and correct copy of a letter from Barbara Rudolph, counsel to Wyeth, to Eric Lane, counsel to Impax and Joseph Gratz, counsel to Impax, dated May 8, 2007 is attached hereto as Exhibit G.

10. A true and correct copy of a letter from Barbara Rudolph, counsel to Wyeth, to Daniel Kassabian, counsel to Impax, dated May 3, 2007 is attached hereto as Exhibit H.

11. A true and correct copy of a letter from Daniel Kassabian, counsel to Impax, to Barbara Rudolph, counsel to Wyeth, dated April 19, 2007 is attached hereto as Exhibit I.

12. A true and correct copy of a letter from Eric Lane, counsel to Impax, to Barbara Rudolph, counsel to Wyeth, dated May 8, 2007 is attached hereto as Exhibit J.

13. A true and correct copy of Impax Laboratories, Inc.'s Responses to Wyeth First Request for Admission is attached hereto as Exhibit K.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed at Wilmington, Delaware on May 9, 2007.

  
\_\_\_\_\_  
MARY B. MATTERER (C.D. No. 2696)

# **EXHIBIT A**

# **ENTIRE EXHIBIT UNDER SEAL**

# **EXHIBIT B**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

Civil Action No.: 06-222 JJF

**DEFENDANT IMPAX LABORATORIES, INC.'S  
FIRST SET OF REQUESTS FOR ADMISSION (NOS. 1-6)**

Pursuant to Federal Rule of Civil Procedure 36, Defendant Impax Laboratories, Inc. ("Impax") requests that Plaintiff Wyeth ("Wyeth") respond in writing to the Requests for Admission set forth below within 30 days.

**DEFINITIONS**

When used in the following Requests for Admission, the following definitions apply:

1. "WYETH" means Plaintiff Wyeth and that company as it was previously named and any related companies, parents, divisions, or subsidiaries, past or present, located in the U.S. or abroad, and the past or present directors, officers, employees, agents, representatives or attorneys thereof.
2. "PATENTS IN SUIT" means U.S. Patent No. 6,274,171 B1, U.S. Patent No. 6,403,120 B1, U.S. Patent No. 6,419,958 B2.
3. "PUBLICLY AVAILABLE" is defined to encompass the meaning of a "printed publication" as that term is understood in connection with 35 U.S.C. § 102.

**INSTRUCTIONS**

- A. The matters in these Requests for Admission shall be deemed admitted unless the answer specifically denies the matter or sets forth in detail the reasons why

WYETH cannot truthfully admit or deny the matter. A denial shall meet the substance of the request, and when good faith requires that WYETH qualify an answer or deny only a part of the matter of which admission is requested, WYETH shall specify so much of it as is true and qualify or deny the remainder. Lack of information or knowledge shall not be given as a reason for failure to admit or deny unless it is stated that reasonable inquiry has been made and that the information known or readily obtainable is insufficient to enable WYETH to admit or deny the request.

B. If any Request for Admission is unclear or ambiguous to you, you are requested to contact undersigned counsel as soon as possible so that the Request for Admission can be clarified to avoid unnecessary delays in discovery.

#### **REQUESTS FOR ADMISSION**

1. WYETH is requested to admit, separately for each reference listed in Exhibits A and B, that the document is a true and correct duplicate of the original document, accurately states and reflects the title, date, and authorship of said original, and is authentic within the meaning of Federal Rule of Evidence 901.

2. WYETH is requested to admit, separately for each reference listed in Exhibit A, that the reference was PUBLICLY AVAILABLE on or before March 25, 1995.

3. WYETH is requested to admit, separately for each reference listed in Exhibit B, that the reference was PUBLICLY AVAILABLE on or before November 5, 1996.


4. Admit that if the Court construes the term "extended release formulation" to mean a formulation comprising, *inter alia*, microcrystalline cellulose, the submission by Impax to the FDA of ANDA No. 78-057 does not literally infringe the asserted claims of the PATENTS-IN-SUIT.



5. Admit that the compound in Wyeth's product EFFEXOR XR® known as venlafaxine hydrochloride was claimed by U.S. Patent No. 4,535,186, assigned to WYETH.

6. Admit that Wyeth's product EFFEXOR® was available to the public as of March 25, 1995.

Dated: February 27, 2007

  
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JOHN M. BENASSI (*pro hac vice*)  
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Attorneys for Defendant  
IMPAX LABORATORIES, INC.

**Exhibit A**

- 1) WO 94/27589 to Edgren *et al.*, assigned to Alza Corp **IMPAX0214525 - IMPAX0214560**
- 2) EP 0 624 366, to Miller *et al.*, assigned to Euroceltique S.A. **IMPAX0214061 - IMPAX0214077**
- 3) AU 47732/90, to Morella *et al.*, assigned to F.H. Faulding & Co., Ltd. **IMPAX0213848 - IMPAX0213906**
- 4) US 4,138,475 to McAinsh *et al.*, assigned to Imperial Chemical Industries, Ltd. **IMPAX0214306 - IMPAX0214308**
- 5) US 4,761,501, to Husbands, *et al.*, assigned to American Home Products Corporation **IMPAX0214263 - IMPAX0214276**
- 6) Hicks, *et al.*, *Therapeutic Drug Monitoring* (1994) 16:100-107. "A high performance liquid chromatographic method for the simultaneous determination of venlafaxine and O-desmethylvenlafaxine in biological fluids" **IMPAX0214126 - IMPAX0214133**
- 7) COMPENDIUM OF PHARMACEUTICALS AND SPECIALTIES 30th Ed. (1995) Canadian Pharmaceutical Association; CK Production. **IMPAX0213934 - IMPAX0213939**
- 8) Gupta "Oral Controlled Release Delivery" pp 255-314 in TREATISE ON CONTROLLED DRUG DELIVERY, Kydonieus, Ed. Dekker (1992) **IMPAX0411094 - IMPAX0411162**
- 9) Pharmaceutical Research and Manufacturers of America, "In Development: New Medicines for Women" (September 1994) pp. 1-24 **IMPAX0411070 - IMPAX0411093**

10) Ritschel, HANDBOOK OF BASIC PHARMACOKINETICS 4th Ed. Hamilton, Ill.: Drug Intelligence Publications, (1992), **IMPAX0411064 - IMPAX0411069**

11) Troy *et al.*, *J Clin Pharmacol* (1995) 35:404-409 "The pharmacokinetics of venlafaxine when given in a twice-daily regimen" **IMPAX0214246 - IMPAX0214251**

12) REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 19th Ed., Alfonso R. Gennaro, Ed. Easton, Pa.: Mack Pub. Co., (1995), **IMPAX0411051 - IMPAX0411063**

**Exhibit B**

1) WO 95/14460, to Sackler *et al.*, assigned to Euroceltique, S.A.  
**IMPAX0214561 - IMPAX0214638**

2) WO 94/27589 to Edgren *et al.*, assigned to Alza Corp **IMPAX0214525 -  
IMPAX0214560**

3) EP 0 624 366, to Miller *et al.*, assigned to Euroceltique S.A.  
**IMPAX0214061- IMPAX0214077**

4) AU 47732/90, to Morella *et al.*, assigned to F.H. Faulding & Co., Ltd.  
**IMPAX0213848 - IMPAX0213906**

5) US 4,138,475 to McAinsh *et al.*, assigned to Imperial Chemical Industries,  
Ltd. **IMPAX0214306 - IMPAX0214308**

6) US 4,761,501, to Husbands, *et al.*, assigned to American Home Products  
Corporation **IMPAX0214263 - IMPAX0214276**

7) Troy *et al.*, *J Clin Pharmacol* (1995) 35:404-409 "The pharmacokinetics  
of venlafaxine when given in a twice-daily regimen" **IMPAX0214246 - IMPAX0214251**

8) Hedges *et al.*, *Psychopharmacol Bull.* (1995) 31(4):779-83. "An open  
trial of venlafaxine in adult patients with attention deficit hyperactivity disorder"  
**IMPAX0214121 - IMPAX0214125**

9) Hicks, *et al.*, *Therapeutic Drug Monitoring* (1994) 16:100-107. "A high  
performance liquid chromatographic method for the simultaneous determination of  
venlafaxine and O-desmethylenlafaxine in biological fluids" **IMPAX0214126 -  
IMPAX0214133**

10) REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 19th Ed., Alfonso  
R. Gennaro, Ed. Easton, Pa.: Mack Pub. Co., (1995), **IMPAX0411051 - IMPAX0411063**

11) Ritschel, HANDBOOK OF BASIC PHARMACOKINETICS 4th Ed. Hamilton, Ill.: Drug Intelligence Publications, (1992), **IMPAX0411064 - IMPAX0411069**

12) Gupta "Oral Controlled Release Delivery" pp 255-314 in TREATISE ON CONTROLLED DRUG DELIVERY, Kydonieus, Ed. Dekker (1992) **IMPAX0411094 - IMPAX0411162**

13) COMPENDIUM OF PHARMACEUTICALS AND SPECIALTIES 30th Ed. (1995) Canadian Pharmaceutical Association; CK Production. **IMPAX0213934 - IMPAX0213939**

14) Pharmaceutical Research and Manufacturers of America, "In Development: New Medicines for Women" (September 1994) pp. 1-24 **IMPAX0411070 - IMPAX0411093**

# **EXHIBIT C**

# **ENTIRE EXHIBIT UNDER SEAL**

# **EXHIBIT D**



# **ENTIRE EXHIBIT UNDER SEAL**

# **EXHIBIT E**

# **ENTIRE EXHIBIT UNDER SEAL**

# **EXHIBIT F**

# HellerEhrman<sub>LLP</sub>

May 9, 2007

*Via Email Transmission and U.S. Mail*

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Barbara R. Rudolph, Esq.  
Finnegan Henderson Farabow  
Garrett & Dunner LLP  
901 New York Avenue, N.W.  
Washington, D.C. 20001-4413

Re: Wyeth v. Impax Laboratories, Inc.  
U.S. District Court, District of Delaware, Civil Action No. 06-222 JJF

Dear Barbara:

We write regarding your letter of May 8, 2007 summarizing our May 7, 2007 meet and confer. This responds to the portions of your letter and the telephone conference regarding Wyeth's Responses to Impax's Request for Admission Nos. 1-3, 50 and 62 and some outstanding documents from the *Teva* litigation.

You informed us that Wyeth has thus far been unable to locate its opposition brief to Motion in Limine No. 8 from the *Teva* litigation, but is still trying. We appreciate the lengths to which Wyeth is going in order to locate this document. Please keep us posted as to the progress of this search.

As to Wyeth's Responses to Request for Admission Nos. 1-3, we first confirm that we do not ask Wyeth to stipulate to the accuracy of any assignments listed on these documents; we only seek stipulations of authenticity (i.e., that the documents are true and correct copies) and publication date. During the meet and confer, we agreed that Wyeth would stipulate to the authenticity of journal articles if Impax provides clean and complete copies with journal cover sheets and tables of contents, subject to Wyeth's individual review of the articles. However, we understand from your letter that Wyeth still insists on certified copies of U.S. and foreign patents and published applications (with a declaration instead of certification for foreign patent documents if certification is difficult to obtain). We do not understand why Wyeth cannot authenticate clean copies of patents and applications obtained from U.S. and other patent office web sites. We also do not understand why Wyeth cannot authenticate these documents with the proviso that the authentic document does not include any writings, interlineations or the like that may have been added. Impax will seek to recover costs for the

Heller Ehrman LLP 4350 La Jolla Village Drive, 7<sup>th</sup> Floor San Diego, CA 92122 [www.hellerehrman.com](http://www.hellerehrman.com)

Anchorage	Beijing	Hong Kong	Los Angeles	Madison, WI	New York	San Diego	San Francisco	Seattle
			Silicon Valley	Singapore	Washington, D.C.			

HellerEhrman LLP

Barbara R. Rudolph, Esq.  
May 9, 2007  
Page 2

resources it will be forced unnecessarily to expend to obtain certified copies of patent documents whose authenticity is not reasonably subject to dispute.

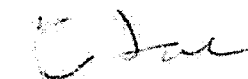
You proposed that we agree to permit Wyeth to delay its response to Request Nos. 50 and 62 until we proceed with expert discovery, and in exchange, Impax could similarly delay its response to certain Wyeth Requests for Admission. In view of the fact that Impax served its Responses to Wyeth's Requests for Admission over 9 months ago (July 26, 2006) and served Amended Responses to three of Wyeth's Requests in February 2007 without complaint from Wyeth, we do not see this as a true compromise.

As to the substance of Request Nos. 50 and 62 and Wyeth's objections, we reiterate that they involve fact questions, or at most, mixed questions of fact and law, to which we believe we are entitled to responses. We further submit that Wyeth's objection that the requests seek expert opinion is without merit. To the extent that Wyeth has corporate knowledge of these issues, we believe we are entitled to responses, irrespective of whether an expert may have an opinion on these matters.

I also note that the Impax Responses to Wyeth's Requests for Admission you have cited in support of your position are inapposite. Your May 3, 2007 letter to Daniel N. Kassabian states that Impax is in no position to dispute Wyeth's objection based on a "legal opinion" because Impax made a similar objection to Wyeth's Request to Admit No. 44. However, Request No. 44 seeks an admission that "[a]n AB rating from the FDA signifies that a generic version of a brand name prescription pharmaceutical is bioequivalent and therapeutically equivalent to the corresponding branded drug." This seeks a pure legal conclusion and implicates no underlying facts whatsoever, and is therefore very different from Impax's Request Nos. 50 and 62 regarding what factual knowledge was in the public domain prior to May 25, 1995. Also, in the meet and confer yesterday, you argued that our position on Request Nos. 50 and 62 was inconsistent with our Response to Wyeth's Request for Admission No. 15. Although Impax objected to this request regarding encapsulation of Impax's products based on expert opinion, *Impax admitted this request*. By contrast, Wyeth has refused to provide any substantive response to Request Nos. 50 and 62. If Wyeth wishes to admit (or to deny) Request Nos. 50 and 62 subject to objections, we see no immediate need to seek redress from the Court. If Wyeth continues in its refusal to admit or deny these Requests, however, we will be forced to file a Motion to Compel.

We hope you will reconsider your position on these two requests.

Very truly yours,



Eric L. Lane

HellerEhrman<sub>LLP</sub>

Barbara R. Rudolph, Esq.  
May 9, 2007  
Page 3

cc: M. Patricia Thayer, Esq.  
John M. Benassi, Esq.  
Jessica R. Wolff, Esq.  
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Daniel Kassabian, Esq.  
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Paula L. Blizzard, Esq.  
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Basil J. Lewris, Esq.  
James K. Hammond, Esq.  
Linda A. Wadler, Esq.  
John L. Marquardt, Esq.  
Karen Jacobs Loudon, Esq.

# **EXHIBIT G**





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May 8, 2007

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*Via Email and Confirmation  
Copy via U.S. Mail*

Joseph C. Gratz, Esq.  
Keker & Van Nest LLP  
710 Sansome Street  
San Francisco, CA 94111

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Counsel:

We write to memorialize the agreements and discussions of our May 7, 2007 telephone conference.

During our previous teleconference of May 4, 2007, Daniel Kassabian agreed that Impax would formally withdraw its allegation of litigation misconduct that it had made in Mr. Kassabian's letter to us dated April 13, 2007. We understand from yesterday's telephone conference that Mr. Kassabian is in the process of drafting a letter to that effect, which we should expect to receive by the end of this week. We also understand that Mr. DuBoise has all of Wyeth's production CD's collected and that we may expect to receive them by the end of the week as well.

Wyeth, in turn, agreed to provide Impax with Excel tables for WYPROD\_106, documents listing the image keys for each image produced in this volume, and the image key from the master load file corresponding to the beginning of the document. We will likewise provide similar information for documents of the WYPROD\_105 and WYPROD\_107 series. We should be able to provide that information by the end of the week.

We also discussed Wyeth's responses to Impax's Requests for Admission Nos. 1-3, 50 and 62. As to Requests for Admission Nos. 1-3, we raised two distinct issues.

Eric Lane, Esq.  
Joseph C. Gratz, Esq.  
May 8, 2007  
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FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

First, we explained how these Requests implicitly demanded that Wyeth independently verify the assignment of various documents referred to in the requests and that Wyeth would not agree to undertake this burden. We understand that Impax will consider withdrawing this aspect of its requests.

Second, we discussed the lack of indicia of authenticity associated with many of the documents that are the subject of Requests for Admission Nos. 1-3, including the lack of cover pages or tables of contents for articles, and spurious markings including handwriting. We suggested that the parties arrive at a mutually agreeable approach regarding the evidentiary requirements for certain categories of documents. As an initial proposal, we suggested that the parties agree to providing the following:

- Complete documents should be provided if possible without extraneous markings (other than, for example, library date stamps).
- Published articles should be accompanied by a cover page indicating the source of the document, a table of contents, where appropriate; and some reasonable indication of publication and/or receipt date.
- United States Patent documents should be certified copies.
- Foreign patent documents should also be certified, but because it may be difficult to obtain certified copies of foreign patent documents Wyeth proposed that the party proffering the document provide a declaration from counsel or other appropriate person indicating the source of the foreign patent document, noting any extraneous markings, and averring that the document is, to the best of his/her knowledge, what it purports to be. Similar declarations may be appropriate in the event that clean copies of other materials cannot be reasonably located.

We look forward to your response to this proposal.

We also discussed Wyeth's objections to Request for Admission Nos. 50 and 62; most particularly, that they prematurely seek expert opinion. We proposed that the parties might arrive at a compromise by which responses to certain requests for admission including Wyeth's answers to Request for Admission Nos. 50 and 62, could be deferred until expert discovery. If Impax agrees in principle with this approach, we will provide a more detailed proposal. Please note however, that Wyeth will not agree to allowing Impax to defer answering each and every one of Wyeth's Requests for Admission that Impax has thus far refused to answer.

Eric Lane, Esq.  
Joseph C. Gratz, Esq.  
May 8, 2007  
Page 3

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

Finally, we reiterate that we have been unable to locate the opposition brief to Motion in Limine No. 8 from the *Teva* litigation. We have also been unsuccessful thus far in obtaining a copy of this paper from the clerk of the District Court of New Jersey. Should this document become available to us we will forward a copy to you in due course.

Sincerely,



Barbara R. Rudolph

cc: Jessica Wolff, Esq. (via e-mail)  
Samuel F. Ernst, Esq. (via e-mail)  
Daniel N. Kassabian, Esq. (via e-mail)  
Mary B. Matterer, Esq. (via e-mail)  
Paula L. Blizzard, Esq. (via e-mail)

# **EXHIBIT H**

# **ENTIRE EXHIBIT UNDER SEAL**

# **EXHIBIT I**

# **ENTIRE EXHIBIT UNDER SEAL**

# **EXHIBIT J**



# HellerEhrman<sub>LLP</sub>

May 8, 2007

*Via Email Transmission and U.S. Mail*

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**Re: Wyeth v. Impax Laboratories, Inc.**  
**U.S. District Court, District of Delaware, Civil Action No. 06-222 JJF**

Dear Barbara:

This responds to the portion of your letter of May 3, 2007 to Daniel Kassabian addressing Wyeth's Response to Request for Admission No. 31.

As you suggested, we conducted a simple comparison of the text added in U.S.S.N. 08/964,328, filed on November 5, 1997, to the final text in U.S. Patent No. 6,274,171. The only difference we could discern is that "hydroxypropylmethylcellulose" is written as one word at Column 6, line 11 in the '171 patent, whereas it is written as two words (i.e., "hydroxypropylmethyl cellulose") in the '328 application as filed. Is this distinction the basis for Wyeth's qualified Response to Request for Admission No. 31 that the text is "substantially similar" rather than providing a simple admission?

Please let us know by close of business tomorrow (E.S.T.) if there is any other difference between the passage referenced in Request for Admission No. 31 as filed and the passage as it appears in the '171 patent. We simply seek a straightforward response to that request, and we hope not to ask the Court for assistance.

Very truly yours,



Eric L. Lane

HellerEhrman LLP

Barbara R. Rudolph, Esq.  
May 8, 2007  
Page 2

cc: M. Patricia Thayer, Esq.  
John M. Benassi, Esq.  
Jessica R. Wolff, Esq.  
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Daniel Kassabian, Esq.  
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Mary B. Matterer, Esq.  
Basil J. Lewris, Esq.  
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Linda A. Wadler, Esq.  
John L. Marquardt, Esq.  
Karen Jacobs Loudon, Esq.

SD 876046 v1

# **EXHIBIT K**

# **ENTIRE EXHIBIT UNDER SEAL**

**CERTIFICATE OF SERVICE**

I hereby certify that on this 16<sup>th</sup> day of May 2007, I electronically filed the foregoing document, **REDACTED VERSION OF DECLARATION OF MARY B. MATTERER IN SUPPORT OF DEFENDANT IMPAX LABORATORIES, INC.'S MOTION TO COMPEL RESPONSES TO DEFENDANT'S REQUEST FOR ADMISSION NOS. 1-3, 31, 38, 50, 62, 67 AND 68**, with the Clerk of the Court using CM/ECF which sent notification of such filing to the following:

Jack B. Blumenfeld  
Karen Jacobs Loudon  
Morris Nichols Arsht & Tunnell  
1201 N. Market Street  
Wilmington, DE 19801

Additionally, I hereby certify that on the same date, the foregoing document was served as indicated below:

**VIA EMAIL**

Jack B. Blumenfeld  
Karen Jacobs Loudon  
Morris Nichols Arsht & Tunnell  
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/s/ Mary B. Matterer  
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*Attorneys for IMPAX LABORATORIES, INC.*